



# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 010051 0103 Rev. 06**

**Manufacturer:** **Abbott GmbH**  
Max-Planck-Ring 2  
65205 Wiesbaden  
GERMANY

**Product Category(ies): Products for determination of infection markers**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1\\_010051\\_0103 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:V1_010051_0103_Rev.06)

**Report no.:** 713186103

**Valid from:** 2020-09-16

**Valid until:** 2021-11-10

**Date,** 2020-09-16

Christoph Dicks  
Head of Certification/Notified Body



Benannt durch/Designated by  
 Zentralstelle der Länder  
 für Gesundheitsschutz  
 bei Arzneimitteln und  
 Medizinprodukten  
 www.zlg.de  
 ZLG-BS-245.10.07



Product Service

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**Model(s):**

**Products for the determination  
 of infection markers for HIV, Hepatitis B,  
 Hepatitis C, HTLV, toxoplasmosis**

**Facility(ies):**

Abbott GmbH  
 Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY



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The products detailed below are covered under the scope of this certificate:

## Annex II List A Products

Product Name	REF N°
ABBOTT PRISM HIV O Plus Assay Kit	3D34-48
ABBOTT PRISM HBsAg Assay Kit	3A47-48
ABBOTT PRISM HCV Assay Kit	6A52-48
ABBOTT PRISM HTLV-I/HTLV-II Assay Kit	6A53-48
ABBOTT PRISM Positive Run Control Kit	5E22-11
ABBOTT PRISM Run Control Kit	5E22-10
ABBOTT PRISM HBcore Assay Kit	1A77-48
ABBOTT PRISM HBsAg Confirmatory Assay Kit	6D16-48
ABBOTT PRISM HIV Ag/Ab Combo Assay Kit	7G46-48
ABBOTT PRISM Run Control Kit	2K24-10
ABBOTT PRISM Positive Run Control Kit	2K24-11
ARCHITECT Anti-HCV Reagent Kit	6C37-22
ARCHITECT Anti-HCV Reagent Kit	6C37-27
ARCHITECT Anti-HCV Reagent Kit	6C37-32
ARCHITECT Anti-HCV Reagent Kit	6C37-37
ARCHITECT Anti-HCV Calibrator	6C37-01
ARCHITECT Anti-HCV Controls	6C37-10
ARCHITECT Anti-HCV Reagent Kit	6C37-28
ARCHITECT Anti-HCV Reagent Kit	6C37-33
ARCHITECT Anti-HCV Reagent Kit	6C37-38
ARCHITECT Anti-HCV Calibrator	6C37-02
ARCHITECT Anti-HCV Controls	6C37-15
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-22
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-27
ARCHITECT Anti-HBc IgM Calibrators	6C33-02
ARCHITECT Anti-HBc IgM Controls	6C33-11



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## Annex II List A Products

Product Name	REF N°
ARCHITECT Anti-HBe Reagent Kit	6C34-20
ARCHITECT Anti-HBe Reagent Kit	6C34-25
ARCHITECT Anti-HBe Reagent Kit	6C34-35
ARCHITECT Anti-HBe Calibrator	6C34-01
ARCHITECT Anti-HBe Controls	6C34-10
ARCHITECT HBeAg Reagent Kit	6C32-20
ARCHITECT HBeAg Reagent Kit	6C32-25
ARCHITECT HBeAg Reagent Kit	6C32-27
ARCHITECT HBeAg Reagent Kit	6C32-37
ARCHITECT HBeAg Calibrators	6C32-01
ARCHITECT HBeAg Quantitative Calibrators	7P24-01
ARCHITECT HBeAg Controls	6C32-10
ARCHITECT HBeAg Quantitative Controls	7P24-10
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-22
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-27
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-32
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-37
ARCHITECT HIV Ag/Ab Combo Calibrator	4J27-03
ARCHITECT HIV Ag/Ab Combo Controls	4J27-12
ARCHITECT rHTLV I/II Reagent Kit	6L61-25
ARCHITECT rHTLV I/II Reagent Kit	6L61-30
ARCHITECT rHTLV I/II Reagent Kit	6L61-35
ARCHITECT rHTLV I/II Calibrator	6L61-01
ARCHITECT rHTLV I/II Controls	6L61-10
ARCHITECT Anti-HBc II Reagent Kit	8L44-25
ARCHITECT Anti-HBc II Reagent Kit	8L44-30
ARCHITECT Anti-HBc II Reagent Kit	8L44-35
ARCHITECT Anti-HBc II Calibrator	8L44-01
ARCHITECT Anti-HBc II Controls	8L44-10



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## Annex II List A Products

Product Name	REF N°
ARCHITECT HCV Ag Reagent Kit	6L47-29
ARCHITECT HCV Ag Calibrators	6L47-02
ARCHITECT HCV Ag Controls	6L47-11
Alinity i Anti-HBe Reagent Kit	07P6322
Alinity i Anti-HBe Calibrator	07P6301
Alinity i Anti-HBe Controls	07P6310
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0722
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0732
Alinity i HIV Ag/Ab Combo Calibrator	08P0701
Alinity i HIV Ag/Ab Combo Controls	08P0710
Alinity i Anti-HCV Reagent Kit	08P0622
Alinity i Anti-HCV Reagent Kit	08P0632
Alinity i Anti-HCV Calibrator	08P0601
Alinity i Anti-HCV Controls	08P0610
Alinity i Anti-HCV Reagent Kit	08P0623
Alinity i Anti-HCV Reagent Kit	08P0633
Alinity i Anti-HCV Calibrator	08P0602
Alinity i Anti-HCV Controls	08P0611
Alinity i Anti-HBc IgM Reagent Kit	07P8622
Alinity i Anti-HBc IgM Calibrators	07P8601
Alinity i Anti-HBc IgM Controls	07P8610
Alinity i Anti-HBc II Reagent Kit	07P8722
Alinity i Anti-HBc II Reagent Kit	07P8732
Alinity i Anti-HBc II Calibrator	07P8701
Alinity i Anti-HBc II Controls	07P8710
Alinity i HCV Ag Reagent Kit	09P2322
Alinity i HCV Ag Controls	09P2310
Alinity i HCV Ag Calibrators	09P2301
Alinity i rHTLV-I/II Reagent Kit	07P6122
Alinity i rHTLV-I/II Reagent Kit	07P6132
Alinity i rHTLV-I/II Calibrator	07P6101
Alinity i rHTLV-I/II Controls	07P6110



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## Annex II List A Products

Product Name	REF N°
Alinity i HBeAg Reagent Kit	07P6422
Alinity i HBeAg Calibrators	07P6401
Alinity i HBeAg Controls	07P6410
Alinity i HBeAg Quantitative Calibrators	09P1001
Alinity i HBeAg Quantitative Controls	09P1010
Alinity s Anti-HBc Reagent Kit	06P0655
Alinity s Anti-HBc Calibrator Kit	06P0602
Alinity s Anti-HBc Assay Control Kit	06P0610
Alinity s Anti-HBc Release Control Kit	06P0612
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0155
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0102
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0110
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0112
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0160
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0103
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0120
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0124
Alinity s Anti-HCV Reagent Kit	06P0455
Alinity s Anti-HCV Calibrator Kit	06P0402
Alinity s Anti-HCV Assay Control Kit	06P0410
Alinity s Anti-HCV Release Control Kit	06P0412
Alinity s Anti-HCV Reagent Kit	06P0477
Alinity s Anti-HCV Calibrator Kit	06P0409
Alinity s Anti-HCV Assay Control Kit	06P0419
Alinity s Anti-HCV Release Control Kit	06P0418
Alinity s Anti-HCV Reagent Kit	06P0460
Alinity s Anti-HCV Calibrator Kit	06P0403
Alinity s Anti-HCV Assay Control Kit	06P0420
Alinity s Anti-HCV Release Control Kit	06P0424
Alinity s HTLV I/II Reagent Kit	06P0755
Alinity s HTLV I/II Calibrator Kit	06P0702
Alinity s HTLV I/II Assay Control Kit	06P0710
Alinity s HTLV I/II Release Control Kit	06P0712
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0177
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0109
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0119
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0118



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**Annex II List A Products for ARCHITECT Platform**

Product Name	REF N°
Anti-HCV Reagent Kit	6C37-74
Anti-HCV Reagent Kit	6C37-77
Anti-HCV Reagent Kit	6C37-78
Anti-HCV Calibrator	6C37-09
Anti-HCV Controls	6C37-19
Anti-HBc IgM Reagent Kit	6C33-74
Anti-HBc IgM Reagent Kit	6C33-75
Anti-HBc IgM Calibrators	6C33-09
Anti-HBc IgM Controls	6C33-19
Anti-HBe Reagent Kit	6C34-74
Anti-HBe Reagent Kit	6C34-77
Anti-HBe Calibrator	6C34-09
Anti-HBe Controls	6C34-19
HBeAg Reagent Kit	6C32-74
HBeAg Reagent Kit	6C32-77
HBeAg Calibrators	6C32-09
HBeAg Quantitative Calibrators	7P24-09
HBeAg Controls	6C32-19
HBeAg Quantitative Controls	7P24-19
HIV Ag/Ab Combo Reagent Kit	4J27-74
HIV Ag/Ab Combo Reagent Kit	4J27-77
HIV Ag/Ab Combo Reagent Kit	4J27-78
HIV Ag/Ab Combo Calibrator	4J27-09
HIV Ag/Ab Combo Controls	4J27-19
Anti-HBc II Reagent Kit	8L44-74
Anti-HBc II Reagent Kit	8L44-77
Anti-HBc II Reagent Kit	8L44-78
Anti-HBc II Calibrator	8L44-09
Anti-HBc II Controls	8L44-19





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## Annex II List A Products for Alinity i Platform

Product Name	REF N°
Anti-HBe Reagent Kit	07P6374
Anti-HBe Calibrator	07P6309
Anti-HBe Controls	07P6319
HIV Ag/Ab Combo Reagent Kit	08P0774
HIV Ag/Ab Combo Reagent Kit	08P0777
HIV Ag/Ab Combo Calibrator	08P0709
HIV Ag/Ab Combo Controls	08P0719
Anti-HCV Reagent Kit	08P0674
Anti-HCV Reagent Kit	08P0677
Anti-HCV Calibrator	08P0609
Anti-HCV Controls	08P0619
Anti-HBc II Reagent Kit	07P8774
Anti-HBc II Reagent Kit	07P8777
Anti-HBc II Calibrator	07P8709
Anti-HBc II Controls	07P8719
Anti-HBc IgM Reagent Kit	07P8674
Anti-HBc IgM Calibrators	07P8609
Anti-HBc IgM Controls	07P8619
HBeAg Reagent Kit	07P6474
HBeAg Calibrators	07P6409
HBeAg Controls	07P6419
HBeAg Quantitative Calibrators	09P1009
HBeAg Quantitative Controls	09P1019





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## Annex II List B Products

Product Name	REF N°
ARCHITECT Toxo IgG Reagent Kit	6C19-25
ARCHITECT Toxo IgG Reagent Kit	6C19-35
ARCHITECT Toxo IgG Calibrators	6C19-01
ARCHITECT Toxo IgG Controls	6C19-10
ARCHITECT Toxo IgG Avidity Reagent Kit	6L37-25
ARCHITECT Toxo IgG Avidity Calibrator & Controls	6L37-11
ARCHITECT Toxo IgM Reagent Kit	6C20-25
ARCHITECT Toxo IgM Reagent Kit	6C20-35
ARCHITECT Toxo IgM Calibrator	6C20-01
ARCHITECT Toxo IgM Controls	6C20-10
Alinity i Toxo IgG Reagent Kit	07P4522
Alinity i Toxo IgG Reagent Kit	07P4532
Alinity i Toxo IgG Calibrators	07P4501
Alinity i Toxo IgG Controls	07P4510
Alinity i Toxo IgM Reagent Kit	07P4722
Alinity i Toxo IgM Reagent Kit	07P4732
Alinity i Toxo IgM Calibrator	07P4701
Alinity i Toxo IgM Controls	07P4710
Alinity i Toxo IgG Avidity Reagent Kit	07P4622
Alinity i Toxo IgG Avidity Controls	07P4610



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### Annex II List B Products for ARCHITECT Platform

Product Name	REF N°
Toxo IgG Calibrators	6C19-09
Toxo IgG Controls	6C19-19
Toxo IgG Reagent Kit	6C19-74
Toxo IgG Reagent Kit	6C19-77
Toxo IgM Calibrators	6C20-09
Toxo IgM Controls	6C20-19
Toxo IgM Reagent Kit	6C20-74
Toxo IgM Reagent Kit	6C20-77
Toxo IgG Avidity Reagent Kit	6L37-74

### Annex II List B Products for Alinity Platform

Product Name	REF N°
Toxo IgG Calibrators	07P4509
Toxo IgG Controls	07P4519
Toxo IgG Reagent Kit	07P4574
Toxo IgG Reagent Kit	07P4577
Toxo IgM Calibrators	07P4709
Toxo IgM Controls	07P4719
Toxo IgM Reagent Kit	07P4774
Toxo IgM Reagent Kit	07P4777
Toxo IgG Avidity Reagent Kit	07P4674